IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAMMY RAUL, Derivatively on Behalf of Nominal Defendant SPECTRUM PHARMACEUTICALS INC., Plaintiff, v. JOSEPH W. TURGEON, KURT A. GUSTAFSON, FRANCOIS LEBEL, WILLIAM L. ASHTON, NORA E. BRENNAN, SETH H.Z. FISCHER, JUHYUN LIM, THOMAS J. RIGA, JEFFREY l. VACIRCA, DOLATRAI M. VYAS, BERNICE R. WELLES, Defendants, and SPECTRUM PHARMACEUTICALS INC., Nominal Defendant.	Case No. **JURY TRIAL DEMANDED**

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

By and through her undersigned counsel, Plaintiff Tammy Raul ("Plaintiff") brings this shareholder derivative action on behalf of Nominal Defendant Spectrum Pharmaceuticals Inc. ("Spectrum" or the "Company") and against certain current and former officers and directors of the Company for breaches of fiduciary duties, unjust enrichment, abuse of control and gross mismanagement. Plaintiff makes these allegations upon personal knowledge as to those allegations concerning himself and, as to all other matters, upon the investigation of counsel, which includes without limitation: (a) review and analysis of public filings made by Spectrum and other related parties with the United States Securities and Exchange Commission ("SEC"); (b) review and

analysis of press releases and other publications disseminated by certain of the Defendants (defined below) and other related non-parties; (c) review of news articles, shareholder communications, and postings on Spectrum's website concerning the Company's public statements; (d) pleadings, papers, and any documents filed with, and publicly available from, the related consolidated securities fraud class action lawsuit captioned *Chung Luo v. Spectrum Pharmaceuticals, Inc.*, Case No. 2:21-cv-01612 (D. Nev.) (the "Related Securities Class Action"); and (e) review of other publicly-available information concerning Spectrum and the Defendants.

NATURE OF THE ACTION

1. Plaintiff brings this action derivatively for the benefit of Nominal Defendant Spectrum against certain of the Company's current and former executive officers and directors aiming to rectify the Defendants' violations of the Exchange Act and breaches of fiduciary duties for issuing false and misleading statements and/or omitting material information in the Company's public filings and proxy statements from approximately December 27, 2018 to the present (the "Relevant Period").[1]

2. Spectrum is a biopharmaceutical company that develops and commercializes oncology and hematology drug products. The Company's products under development include, among others, ROLONTIS (eflapegrastim), a novel long-acting granulocyte colony-stimulating factor for chemotherapy-induced neutropenia.

3. In December 2018, Spectrum submitted a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for ROLONTIS as a treatment for chemotherapy-induced neutropenia (the "ROLONTIS BLA").

[1] The materially misleading statements and/or omissions were issued in the Company's financial reports and other public filings and releases from approximately December 27, 2018 to August 5, 2021; however, the wrongs complained of herein continue through to the present as the Company's internal controls remain deficient.

4. Throughout the Relevant Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the ROLONTIS manufacturing facility maintained deficient controls and/or procedures; (ii) the foregoing deficiencies decreased the likelihood that the FDA would approve the ROLONTIS BLA in its current form; (iii) Spectrum had therefore materially overstated the ROLONTIS BLA's approval prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On August 6, 2021, Spectrum announced receipt of a Complete Response Letter ("CRL") from the FDA regarding the ROLONTIS BLA. The CRL cited deficiencies related to manufacturing and indicated that a reinspection of the Company's manufacturing facility will be necessary.

6. On this news, Spectrum's stock price fell $0.70 per share, or 21.54%, to close at $2.55 per share on August 6, 2021.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to the subject matter of this action pursuant to 28 U.S.C. § 1331 because the claims arise under and pursuant to §10(b) of the Exchange Act and Rule 10(b)-5 promulgated thereunder.

8. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. §1367(a), as they relate to Plaintiff's claims under 15 U.S.C. §78n(a).

9. Venue is proper in this Court pursuant to 28 U.S.C. §1391(b), because a substantial portion of the transactions and wrongs complained of herein occurred in this District and defendants have received substantial compensation within this District by doing business here and

engaging in numerous activities that had an effect in this jurisdiction.

THE PARTIES

10. Plaintiff has been a shareholder since prior to the start of the Relevant Period, is currently, and at all relevant times has been, a holder of Spectrum common stock.

11. Defendant Spectrum is incorporated in the United Kingdom and its current principal executive offices are located at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin, Ireland.

12. Defendant Joseph W. Turgeon ("Turgeon") was the Company's President and Chief Executive Officer ("CEO") from December 2017 to December 2021. Defendant Turgeon is named as a defendant in the Related Securities Class Action. In his role as President and Chief Executive Officer for fiscal years 2018, 2019, and 2020, Defendant Turgeon received $4,722,227, $5,697,232, and $3,713,218 in total compensation, respectively.

13. Defendant Kurt A. Gustafson ("Gustafson") was the Company's Executive Vice President and Chief Financial Officer ("CFO") from June 2013 until March 2022. Defendant Gustafson is named as a defendant in the Related Securities Class Action. In his role as Executive Vice President and Chief Financial Officer for fiscal years 2018, 2019, and 2020, Defendant Gustafson received $2,587,373, $3,122,820, and $2,090,952 in total compensation, respectively.

14. Defendant Francois Lebel ("Lebel") has been the Company's Executive Vice President and Chief Medical Officer since November 2018. Defendant Lebel is named as a defendant in the Related Securities Class Action. In his role as Executive Vice President and Chief Medical Officer for fiscal years 2019 and 2020, Defendant Lebel received $2,666,773 and $2,224,518 in total compensation, respectively.

15. Defendants Turgeon, Gustafson, and Lebel are collectively referred to herein as the

"Officer Defendants."

16. Defendant William L. Ashton ("Ashton") has been the Company's Chairman of the Board since June 2019 and a member of the Board since February 2018. In his role as a director of the Company for fiscal years 2018, 2019, and 2020, Defendant Ashton received $544,497, $272,115, and $315,167 in total compensation, respectively.

17. Defendant Nora E. Brennan ("Brennan") has been a member of the Company's Board since December 2020. In her role as a director of the Company for fiscal year 2020, Defendant Brennan received $211,106 in total compensation.

18. Defendant Seth H.Z. Fischer ("Fischer") has been a member of the Company's Board since April 2020. In his role as a director of the Company for fiscal year 2020, Defendant Fischer received $265,882 in total compensation.

19. Defendant Juhyun Lim ("Lim") has been a member of the Company's Board since March 2022.

20. Defendant Thomas J. Riga ("Riga") has been the Company's President, CEO, and member of the Board since January 2022. Previously, Defendant Riga served as the Company's Chief Commercial and Chief Operating Officer. In his role as the Company's President and CEO Defendant Riga stands to receive an annual base salary of $650,000 and will be entitled to an annual discretionary bonus of up to 70% of his base salary, as determined by the Board. In addition, Defendant Riga will receive an equity award of approximately $3,200,000.

21. Defendant Jeffrey L. Vacirca ("Vacirca") has been a member of the Company's Board since November 2018. In his role as a director of the Company for fiscal years 2018, 2019, and 2020, Defendant Vacirca received $213,935, $262,115, and $301,834 in total compensation, respectively.

22. Defendant Dolatrai M. Vyas ("Vyas") has been a member of the Company's Board since June 2013. In his role as a director of the Company for fiscal years 2018, 2019, and 2020, Defendant Dolatrai received $458,218, $257,115, and $290,167 in total compensation, respectively.

23. Defendant Bernice R. Welles ("Welles") has been a member of the Company's Board since June 2018. In her role as a director of the Company for fiscal years 2018, 2019, and 2020, Defendant Welles received $420,718, $267,115, and $300,167 in total compensation, respectively.

24. Defendants Ashton, Brennan, Fischer, Riga, Vacirca, Vyas, and Welles are collectively referred to herein as the "Director Defendants."

25. The Director Defendants, along with the Officer Defendants, are collectively referred to herein as the "Individual Defendants."

26. Related Party Non-Defendant Juhyun Lim ("Lim") has been a member of the Company's Board since January 2022. Lim is named solely for the purposes of demand futility.

FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS

27. By reason of their positions as officers, directors, and/or fiduciaries of Spectrum, and because of their ability to control the business and corporate affairs of Spectrum, the Individual Defendants owed, and owe, the Company and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were, and are, required to use their utmost ability to control and manage Spectrum in a fair, just, honest, and equitable manner. The Individual Defendants were, and are, required to act in furtherance of the best interests of Spectrum and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

28. Each director and officer of the Company owes to Spectrum and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, as well as the highest obligations of fair dealing.

29. In addition, as officers and/or directors of a publicly held company, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's financial and business prospects so that the market price of the Company's stock would be based on truthful and accurate information.

Duties of the Members of the Audit Committee

30. The Company's Audit Committee Charter, effective as of December 10, 2020, states that the purpose of the Audit Committee is to "represent and assist the Board in its general oversight of the Company's accounting and financial reporting processes, audits of the financial statements, internal control and audit functions, and compliance with legal and regulatory requirements."

31. Specifically, the Audit Committee Charter states that the Company's Audit Committee shall (among others):

- review and discuss with management and the independent auditor (a) unaudited interim financial information including the related notes, (b) audited annual financial information including the related notes, (c) the form of audit opinion to be issued by the independent auditor on the audited annual financial statements, and (d) "Management's Discussion and Analysis of Financial Condition and Results of Operations," and determine whether to recommend to the Board that the audited annual financial statements be included in the Company's Annual Report on Form 10-K each year;

- review and discuss with management and the independent auditor: (a) the adequacy and effectiveness of the Company's internal controls (including any significant deficiencies or material weaknesses) and significant changes in internal controls reported to the Committee by the independent auditor or

management; (b) the Company's internal audit procedures; (c) the adequacy and effectiveness of the Company's disclosure controls and procedures, and management reports thereon; and (d) disclosure relating to the Company's internal controls to be included in filings with the SEC;

- review and discuss with management and the independent auditor: (a) any major issues regarding accounting principles and financial statement presentation, including any significant changes in the Company's selection and application of accounting principles; (b) any significant financial reporting issues and judgments made in connection with the preparation of the Company's financial statements, including the effects of alternative GAAP methods; and (c) the effect of regulatory and accounting initiatives and off-balance sheet structures on the Company's financial statements;

- review and discuss with management and the independent auditor various topics and events that may have a significant financial impact on the Company or that are the subject of discussions between management and the independent auditor;

- review risks relating to financial statements, the auditing and financial reporting process, and key credit risks, liquidity risks and market risks and inquire of management, the members of the internal audit function and the independent auditor about the Company's major financial and auditing risks or exposures. The Committee shall discuss with management and, as appropriate, the internal audit function and/or independent auditor, the Company's risk management and risk assessment guidelines and policies relating to the Company's accounting and financial risk exposures and the steps management has taken to monitor and control such exposures. The Committee shall report the results to the Board;

- obtain from the independent auditor assurances that the independent auditor has provided all notices of illegal acts as required by Section 10(b) of the Securities Exchange Act of 1934, as amended;

- discuss with attorneys any legal matters that might have a material impact on the financial statements;

- ensure that the independent auditor completes its audit partner rotation in conformance with applicable law;

- review and discuss with management published financial information and whether and to what extent earnings guidance and similar information shall be disclosed publicly by the Company. This may be conducted generally as to types of information and presentations and need not include advance review of each publication or disclosure;

- review, approve and oversee any related-party transactions (as defined in the applicable SEC rules and regulations, including Item 404 of Regulation S-K) and any other potential conflict of interest situations on an ongoing basis, in accordance with the Company's policies and procedures, including the Company's written policy for approval or ratification of such transactions, and develop policies and procedures for the Committee's approval of related-party transactions, including any transactions which may be pre-approved by the Committee;

- establish and monitor procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters, and the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters. The Committee shall review any such complaints and submissions that have been received, including the current status and the resolution if one has been reached;

- review and approve on a periodic basis, as appropriate, the Company's investment policy;

- prepare the report of the Committee required by and in accordance with the rules, regulations and guidance of the SEC to be included in the Company's annual proxy statement;

- review and discuss with the Company's management and the independent auditor the reliability of the Company's forward-looking statements contained in quarterly and annual reports, proxy statements and earnings press releases disseminated by the Company;

- review and discuss with the Company's management and the independent auditor any off-balance sheet transactions or structures and their effect on the Company's financial results and operations, as well as the disclosure regarding such transactions and structures in the Company's public filings;

32. The full duties of the Audit Committee are set forth in the Company's Audit Committee Charter.[2]

Duties Pursuant to the Company's Code of Business Conduct and Ethics

33. The Individual Defendants, as officers and/or directors of Spectrum, were also bound by the Company's Code of Business Conduct and Ethics (the "Code") (adopted as effective

[2] https://investor.sppirx.com/static-files/8cae3680-32eb-4653-af09-bbbd6cc086a0.

as of May 2020) which, according to the Code, sets out basic principles to guide all directors, officers, and employees of Spectrum, who are required to know and conduct themselves in accordance with the Code, as well as applicable laws and regulations, and to avoid the appearance of improper behavior.

34. Regarding disclosures, the Code states:

> As a public company we are subject to various securities laws, regulations and reporting obligations. Both federal law and our policies require the prompt disclosure of accurate and complete material information regarding the Company's business, financial condition and results of operations. Inaccurate, incomplete or untimely reporting of such information will not be tolerated and can severely damage the Company and cause legal liability. The Company's principal financial officers and other employees working in the accounting function have a special responsibility to ensure that all of our financial disclosures are complete, fair, accurate, timely and understandable. These employees must strive to ensure the Company's financial reporting complies with generally accepted accounting principles and all applicable standards, laws and regulations for accounting and financial reporting of transactions, estimates and forecasts.

Control, Access, and Authority

35. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Spectrum, were able to, and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Spectrum.

36. Because of their advisory, executive, managerial, and directorial positions with Spectrum, each of the Individual Defendants had access to adverse, non-public information about the financial condition, operations, and improper representations of Spectrum.

37. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Spectrum and was at all times acting within the course and scope of such agency.

Reasonable and Prudent Supervision

38. To discharge their duties, the officers and directors of Spectrum were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Spectrum were required to, among other things:

(a) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the investing public;

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) properly and accurately guide shareholders and analysts as to the true financial and business prospects of the Company at any given time, including making accurate statements about the Company's business and financial prospects and internal controls;

(d) remain informed as to how Spectrum conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with securities laws; and

(e) ensure that Spectrum was operated in a diligent, honest, and prudent manner in compliance with all applicable laws, rules, and regulations.

BREACHES OF DUTIES

39. Each Individual Defendant, by virtue of their position as a director and/or officer, owed to Spectrum and its shareholders the fiduciary duties of loyalty and good faith, and the

exercise of due care and diligence in the management and administration of the affairs of Spectrum, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Spectrum, the absence of good faith on their part, and a reckless disregard for their duties to Spectrum and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to Spectrum.

40. The Individual Defendants each breached their duties of loyalty and good faith by allowing the Individual Defendants to cause, or by themselves causing, the Company to make false and/or misleading statements that misled shareholders into believing that disclosures related to the Company's financial and business prospects were truthful and accurate when made.

41. In addition, as a result of the Individual Defendants' illegal actions and course of conduct, the Company is now the subject of the Related Securities Class Action that alleges violations of the federal securities laws. As a result, Spectrum has expended, and will continue to expend, significant sums of money to rectify the Individual Defendants' wrongdoing.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

42. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with, and conspired with, one another in furtherance of their wrongdoing. The Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

43. During all times relevant hereto, the Individual Defendants collectively and individually initiated a course of conduct that was designed to mislead shareholders into believing that the Company's business and financial prospects were better than they actually were. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively

and individually took the actions set forth herein.

44. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (a) disguise the Individual Defendants' violations of law, including breaches of fiduciary duties, unjust enrichment, gross mismanagement, and abuse of control; and (b) disguise and misrepresent the Company's actual business and financial prospects.

45. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company to purposefully, recklessly, or negligently release improper statements. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

46. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commissions of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that wrongdoing, and was aware of their overall contribution to and furtherance of the wrongdoing.

SUBSTATIVE ALLEGATIONS

Background of the Company

47. Spectrum is a biopharmaceutical company that develops and commercializes oncology and hematology drug products. The Company's products under development include, among others, ROLONTIS (elfapegrastim), a novel long-acting granuocyte colony-stimulating factor for chemotherapy-induced neutropenia.

Materially False and Misleading Statements During the Relevant Period

48. The Relevant Period begins on December 27, 2018, when the Company issued a press release, during pre-market hours, announcing its submission of the ROLONTIS BLA with the FDA. That press release stated, in relevant part:

> "ROLONTIS is an important and significant future growth driver for our company," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "Today's milestone brings us one step closer to bringing the first novel G-CSF to healthcare providers in over 15 years in a large market that is familiar to Spectrum."
>
> The BLA for ROLONTIS is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive cytoxic chemotherapy. The study ADVANCE was conducted under a special protocol assessment (SPA) with the Agency. In both studies, ROLONTIS demonstrated the pre-specified hypothesis of non-inferiority (NI) in Duration of Severe Neutropenia (DSN) and a similar safety profile to pegfilgrastim. ROLONTIS also demonstrated non-inferiority to pegfilgrastim in the DSN across all 4 cycles (all NI $p<0.0001$) in both studies.

49. On February 28, 2019, Spectrum filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2018 (the "2018 10-K"). The 2018 10-K stated, in relevant part:

> In December 2015, we reached agreement with the FDA regarding our Phase 3 Special Protocol Assessment, or SPA, for ROLONTIS. This pivotal Phase 3 study (ADVANCE Study, or SPI-GCF-301) was initiated in the first quarter of 2016 to evaluate ROLONTIS as a treatment for chemotherapy-induced neutropenia. We announced in February 2018 that the top line results of this study met the non-inferiority of ROLONTIS to pegfilgrastim endpoint in the Duration of Severe Neutropenia, or DSN, across all four cycles (all $p<0.0001$). We initiated a second pivotal Phase 3 study (RECOVER Study, or SPI-GCF-302) and announced in June 2018, that it had also met its primary efficacy endpoint of non-inferiority in DSN between ROLONTIS and pegfilgrastim.
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> We submitted our Biologics License Application ("BLA") with the FDA in late December 2018. Due to the recent federal government shutdown, the BLA was officially received by the FDA on January 28, 2019. Once this BLA is accepted by the FDA, our Prescription Drug User Fee Act date is expected to be set for 10 months thereafter.

50. Appended to the 2018 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Turgeon and Gustafson, attesting that "the information contained in the [2018 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

51. In connection with the 2018 10-K, Spectrum issued a press release entitled, "Spectrum Pharmaceuticals Reports Fourth Quarter 2018 and Full Year 2018 Financial Results and Pipeline Update." The press release stated, in relevant part:

> "2018 was a very productive year for Spectrum in which our two promising pipeline products significantly progressed in clinical development," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "We begin 2019 with great momentum after meeting the enrollment target for the first cohort in our pivotal poziotinib study and submitting the BLA for ROLONTIS to the FDA at the end of 2018. In 2019, we are laser-focused on continuing to develop our two late-stage products, poziotinib and ROLONTIS, and looking for new opportunities that build upon these assets."

52. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q4 and full year 2018 results (the "Q4 2018 Earnings Call"). During the scripted portion of the Q4 2018 Earnings Call, Defendant Turgeon stated, in relevant part:

> 2018 was a very productive year for Spectrum and my first full year as the CEO and as I reflect on the year there are three major developments in 2018 that I'm very proud of and really defines who we are today. The most significant development in 2018 was the advancement of our pipeline assets, poziotinib and ROLONTIS. 2018 was data rich for both poziotinib and ROLONTIS and the data strengthened our confidence in both of these assets.
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> For ROLONTIS data from two Phase 3 trials demonstrated that it was noninferior and the standard of care with a similar safety profile. We submitted a BLA with the FDA late in December 2018.
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> * * *

> As we look at 2019, poziotinib and ROLONTIS will be our primary focus while we're also exploring opportunities beyond our existing pipeline.

Additionally, when asked a question regarding the Company's cash guidance, Defendant Gustafson responded, "[s]o I think as we take a look at our forecast we feel great about the ROLONTIS data and the BLA filing. So our forecast does include a launch of ROLONTIS sometime in 2020 and so that that is indeed included in that guidance."

53. On March 15, 2019, Spectrum issued a press release announcing its voluntary withdrawal of the ROLONTIS BLA. That press release advised, among other things:

> [D]ue to the [FDA's] request for additional manufacturing-related information for ROLONTIS, the company has voluntarily withdrawn [the ROLONTIS BLA]. Spectrum plans to resubmit a revised BLA as soon as possible.
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> The FDA did not cite concerns related to the pre-clinical and clinical modules of the BLA or the need for additional clinical studies. Spectrum's decision to withdraw the BLA was the result of the company needing more time to provide certain additional manufacturing-related information, which was required before March 29, 2019, the day that the FDA's initial 60-day review period ends.
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> "We are continuing to have productive discussions with the FDA and will deliver the additional information needed to support the application," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "We remain confident in the ROLONTIS program and look forward to a successful resubmission and its ultimate approval."

54. On May 9, 2019, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q1 2019 results (the "Q1 2019 Earnings Call"). During the scripted portion of the Q1 2019 Earnings Call, Defendant Turgeon stated, in relevant part, "[w]e also continue to advance the development of our late stage assets poziotinib and ROLONTIS, the cornerstones of our Company," and "[r]egarding ROLONTIS, we continue to have productive discussions with the FDA and plan to meet with the agency in the near term. We are being thorough and deliberate in our updating our file, do we hope it happen to the FDA as soon as it's ready. We look forward to a successful submission and it's optimal approval."

55. On August 8, 2019, Spectrum issued a press release announcing the Company's Q2 2019 financial results and pipeline update. The press release stated, in relevant part:

> "We've made significant progress on our pipeline in the last few months," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "Most notably, we completed enrollment in our first two poziotinib cohorts in the ZENITH20 study and expect to see results from cohort 1 in the fourth quarter. Based on strong science, we've expanded the poziotinib development program to include additional areas of high unmet medical need in lung cancer. We also had a productive meeting with the FDA and expect to submit the ROLONTIS BLA in the fourth quarter."
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> **ROLONTIS® (eflapegrastim), a novel long-acting GCSF:**
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> - Integrated data from both Phase 3 ROLONTIS clinical trials with 643 patients were presented in a poster session at American Society of Clinical Oncology 2019 annual meeting.
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> - The analysis found that integrated efficacy and safety data from the two identically designed Phase 3 trials - ADVANCE and RECOVER - were consistent with results from the individual trials, demonstrating that ROLONTIS was non-inferior to pegfilgrastim in the reduction of duration of severe neutropenia (DSN) in all four cycles of treatment.
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> - Spectrum met with the FDA and expects to submit the ROLONTIS BLA in the fourth quarter of 2019.

56. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q2 2019 results (the "Q2 2019 Earnings Call"). During the scripted portion of the Q2 2019 Earnings Call, Defendant Turgeon stated, in relevant part:

> Regarding ROLONTIS, our late stage asset to use in chemotherapy-induced neutropenia, we recently had a productive meeting with the FDA and plan to submit the BLA in the fourth quarter. I want to remind you that we have very strong efficacy and safety data coming out of two large Phase III trials. If approved, this product will compete in a multibillion dollar market that I and many members of our management team have a deep expertise in. We look forward to successful submission and its ultimate approval.

Also during the scripted portion of the Q2 Earnings call, Defendant Lebel stated, in relevant part:

> Now, shifting to ROLONTIS, at ASCO, we presented a poster integrating the data from both of our pivotal phase three ROLONTIS clinical trials, which included a total of 643 patients. The integrated analysis of efficiency and safety was consistent with results from the individual studies demonstrating that ROLONTIS was non-inferior to pegfilgrastim in the reduction of duration of severe neutropenia. Regarding our BLA file, we recently had a productive meeting with the FDA to further discuss their expectation around module three, which is the module focused on manufacturing. Based on the outcome of that meeting, we expect to submit the BLA in the fourth quarter of this year.

Finally, in answering a question regarding the "gating factors remaining prior to submitting the [ROLONTIS] BLA," Defendant Turgeon replied, in relevant part, "[l]isten, we are aligned with the FDA. We had our meeting, we got aligned. We're being thorough, we're being deliberate and we're going to filing in the fourth quarter as we said. The questions that we had answered, we're in module three, which is in the SCMC section only. And again, we're being like I said, thorough and deliberate and plan on filing this in the fourth quarter."

57. On October 24, 2019, Spectrum issued a press release announcing its submission of an updated ROLONTIS BLA with the FDA. That press release touted, among other things:

> The BLA for ROLONTIS is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. In both studies, ROLONTIS demonstrated the pre-specified hypothesis of non-inferiority (NI) in Duration of Severe Neutropenia (DSN) and a similar safety profile to pegfilgrastim. ROLONTIS also demonstrated non-inferiority to pegfilgrastim in the DSN across all 4 cycles (all NI $p<0.0001$) in both studies.
>
> "We have submitted a robust package to the FDA that incorporates strong clinical data and addresses previously communicated FDA requests relating to manufacturing processes," said Joe Turgeon, President and CEO of Spectrum. "ROLONTIS could be the first novel G-CSF available to healthcare providers in over 15 years and, if approved, we are looking forward to competing in this multibillion-dollar market."
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> In March 2019, Spectrum voluntarily withdrew the ROLONTIS BLA that it filed with the FDA in 2018. The updated BLA filed today includes additional information in the Chemistry, Manufacturing and Controls (CMC) section.

58. On November 7, 2019, Spectrum issued a press release announcing the Company's Q3 2019 financial results and pipeline update. The press release stated, in relevant part:

> "Spectrum has an expanding pipeline, significant near-term milestones, solid capitalization and a highly focused team," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "In December, we look forward to results from Cohort 1 of our ZENITH20 study investigating poziotinib in lung cancer patients with hard-to-treat mutations. We recently submitted our BLA for ROLONTIS to the FDA, a key milestone, as we continue to execute on our strategic priorities."

59. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q3 2019 results (the "Q3 2019 Earnings Call"). During the scripted portion of the Q3 2019 Earnings Call, Defendant Turgeon stated, in relevant part, "ROLONTIS is our late-stage drug being developed for the treatment of chemotherapy-induced neutropenia. As you recall, we voluntarily withdrew our BLA application earlier this year. Since then, we worked closely with the FDA and recently submitted a robust package. We look forward to competing in this market." Also during the scripted portion of the Q3 2019 Earnings Call, Defendant Lebel stated, in relevant part:

> Now shifting to ROLONTIS. ROLONTIS is a novel long-acting GCSF seeking an indication for the treatment of neutropenia in patient receiving myelosuppressive cancer therapy. On October 24, we submitted an expanded BLA to the FDA. The withdrawal 7 months ago was driven by Module 3 or the CMC section. Since then, we've had productive dialogue with the FDA. We implemented their guidance, provided additional data and rewrote and reorganized certain sections of the file resulting in a strong submission.
>
> As a reminder, our BLA is based on robust clinical data from 2 large pivotal, independent, randomized controlled trials. In both studies, ROLONTIS met the pre-specified end point of non-inferiority in duration of severe neutropenia and met all secondary end points. The safety profile as similar to pegfilgrastim.

60. On December 26, 2019, Spectrum issued a press release providing a pipeline update on the Company's late stage programs. The press release stated, in relevant part:

> The company also announced today that the FDA has accepted for review the BLA for ROLONTIS for the treatment of chemotherapy-induced neutropenia. The

> [Prescription Drug User Fee Act] target action date for the ROLONTIS BLA has been set for October 24, 2020.
>
> "If approved, ROLONTIS could be the first novel granulocyte colony-stimulating factor (G-CSF) available to healthcare providers in over 15 years," said Joe Turgeon. "We have confidence in the future of ROLONTIS and are looking forward to potentially competing in this multibillion-dollar market."
>
> The BLA for ROLONTIS is supported by data from two successful large pivotal Phase 3 clinical trials, ADVANCE (conducted under a SPA) and RECOVER. These trials evaluated the safety and efficacy of ROLONTIS in a total of 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. In both trials, ROLONTIS demonstrated the pre-specified hypothesis of non-inferiority (NI) in duration of severe neutropenia (DSN) and a similar safety profile to pegfilgrastim. ROLONTIS also demonstrated non-inferiority (NI) to pegfilgrastim in the DSN across all 4 cycles of chemotherapy (all NI $p<0.0001$) in both trials.

61. On February 27, 2020, Spectrum issued a press release announcing the Company's Q4 and full year 2019 financial results and pipeline update. The press release stated, in relevant part:

> ROLONTIS is in active review by the FDA and we are preparing to launch shortly following approval," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "We believe this market represents a significant commercial opportunity and our prelaunch activities are well underway. We have a podium presentation on poziotinib in a few short weeks, we have taken steps to adjust our strategy and we have multiple data catalysts in 2020. I look forward to updating you on our progress throughout the year."

62. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q4 and full year 2019 results (the "Q4 2019 Earnings Call"). During the scripted portion of the Q4 2019 Earnings Call, Defendant Turgeon stated, in relevant part:

> ROLONTIS is our late stage drug being developed for the treatment of chemotherapy-induced neutropenia. We submitted our BLA in October of 2019 and it was accepted for filing with the PDUFA date of October 22, 2020. If approved, ROLONTIS could be the first novel granulocyte-colony stimulating factor available to healthcare providers in over 15 years. We have confidence in the future of ROLONTIS and are looking forward to potentially competing in this multibillion dollar market.

63. On March 2, Spectrum filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2019 (the "2019 10-K"). The 2019 10-K listed as one of the Company's recent highlights of its business:

> ***ROLONTIS, a novel long-acting G-CSF:***
>
> We submitted our updated BLA for ROLONTIS with the FDA on October 24, 2019 due to the FDA's request for additional information in the Chemistry, Manufacturing, and Controls section. The updated BLA was accepted by the FDA for review on December 20, 2019. Our BLA is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. Our PDUFA date for the potential approval of ROLONTIS by the FDA has been set for October
> 24, 2020.
>
> In October 2019, integrated results from ADVANCE and RECOVER were presented during a poster session at the 2019 Meeting of the American Society of Clinical Oncology (ASCO) Symposium in San Francisco. The integrated efficacy and safety data from both trials were consistent with results from the individual trials, demonstrating that ROLONTIS was noninferior to pegfilgrastim in the reduction of duration of severe neutropenia in all four cycles of treatment. The integrated data also demonstrated that eflapegrastim provided an absolute risk reduction of severe neutropenia of 6.5% compared to pegfilgrastim in Cycle 1.

64. Appended to the 2019 10-K as exhibits were signed certifications pursuant to SOX by Defendants Turgeon and Gustafson, attesting that "the information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

65. On April 30, 2020, Spectrum issued a press release entitled, "Spectrum Pharmaceuticals Initiates Same Day Dosing Clinical Trial for ROLONTIS® (eflapegrastim)." The press release stated, in relevant part:

> Spectrum [. . .] today announced dosing of the first patient in a clinical trial to evaluate the administration of ROLONTISon the same day as chemotherapy. The trial will evaluate the duration of severe neutropenia when administered at three different time points on the same day following standard chemotherapy in patients

> with early stage breast cancer. ROLONTIS is an investigational drug not approved by the U.S. Food and Drug Administration (FDA) and the BLA is currently under active review by the agency for the treatment of chemotherapy induced neutropenia with a PDUFA date of October 24, 2020.
>
> "This study exemplifies our commitment to unlocking the full potential of ROLONTIS, the first novel biologic positioned to enter the G-CSF market since 2001. A same day dosing option would be a unique and meaningful addition to the G-CSF category," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "We will continue to follow the science and explore ways to add value to patients and health care providers. The initiation of this study, despite the pandemic, highlights investigator's interest and our team's dedication."

66. On May 7, 2020, Spectrum issued a press release announcing the Company's Q1 2020 financial results and pipeline update. The press release stated, in relevant part:

> "The progress in our development pipeline speaks to the investigator interest and the commitment of our team during these unprecedented times," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "The PDUFA date for ROLONTIS remains October 24, 2020 and our updated poziotinib strategy is well under way. We continue to drive the business forward and remain focused on achieving our milestones this year."

67. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q1 2020 results (the "Q1 2020 Earnings Call"). During the scripted portion of the Q1 2020 Earnings Call, Defendant Turgeon stated, in relevant part:

> ROLONTIS is our late-stage drug product candidate that's currently under active review at the FDA for the treatment of chemotherapy-induced neutropenia with a PDUFA date of October 24, 2020. If approved, ROLONTIS could be the first novel granulocyte-colony stimulating factor available to healthcare providers in over 15 years. Our launch preparations for ROLONTIS are actively underway. As the PDUFA date approaches we have already put key leadership personnel in place and will accelerate our commercial build out as we approach the launch date.
>
> We're planning to launch with a lean and effective commercial infrastructure to maximize the impact of ROLONTIS. We're closely monitoring the evolving market dynamics and believe that launching this novel asset will benefit patients, our customers and our shareholders. We're looking forward to its potential approval into competing in this multi-billion dollar growth factor market.

Additionally, when asked about the likelihood of the ROLANTIS Phase 3 clinical trials being accepted by the FDA, Defendant Turgeon responded, in relevant part:

> The two trials we have, number one, there are over 600 patients – 643 patients as I recall - to Phase 3. This is under a SPA, which is a special protocol assessment and what that means, George, is that we worked with the agency, the FDA to develop the actual protocol, which they agreed. We were in tandem with them. They agreed with the protocol. If you have seen the data on both separate Phase 3 or in a presentation of combining the two trials together, the results were outstanding. We hit all our primary and secondary endpoints. Actually, it's what's called a non-inferiority trial. In other words, all we had to demonstrate is we were non-inferior to the standard of care which is the drug that's on the market today, and we certainly did that. You can argue in the first cycle, we actually showed some superiority although it's a non-inferiority trial.
>
> So we feel really good about the data that we've submitted. All I can tell you, it's under active review as we speak. The PDUFA date, which means the date of approval is October 24. That still stands despite the pandemic. We're on active review and active work with the agency, so we're hoping that we can get an approval this year.

68. On August 10, 2020, Spectrum issued a press release announcing the Company's Q2 2020 financial results and corporate update. The press release stated, in relevant part:

> "The recently announced positive results from Cohort 2 are a meaningful development for patients with NSCLC HER2 exon 20 insertion mutations for which there is no approved therapy," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "We are in the process of requesting a pre-NDA meeting with the FDA and look forward to reviewing this data with the agency. In addition, the BLA for ROLONTIS is under active FDA review with a PDUFA date of October 24, 2020. We are in a strong capital position to fund our ongoing development and commercialization of our late stage assets."

69. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q2 2020 results (the "Q2 2020 Earnings Call"). During the scripted portion of the Q2 2020 Earnings Call, Defendant Turgeon stated, in relevant part:

> ROLONTIS our most advanced program is under active review at the FDA for the treatment of chemotherapy-induced neutropenia with a PDUFA date of October 24, 2020. If approved, ROLONTIS could be the first novel granulocyte-colony stimulating factor available to healthcare providers in over 15 years.

> As the PDUFA date approaches, our launch preparations for ROLONTIS are accelerating. I look forward to getting back into this market, an area I know well personally, and the potential of competing in this multi-billion dollar growth factor market.
>
> * * *
>
> I think you can see from everyone's remarks that Spectrum continues to make outstanding progress on our pipeline and our commercial build-out in anticipation of potential approval and launch for ROLONTIS.

70. On October 26, 2020, Spectrum issued a press release announcing that the FDA was deferring its action on the ROLONTIS BLA. The press release stated, in relevant part:

> Spectrum [. . .] today announced that an inspection of the Hanmi Bioplant in South Korea is required before the FDA can approve the company's Biologics License Application (BLA) for ROLONTIS. The FDA was unable to conduct an inspection during the current review cycle due to restrictions on travel related to the COVID-19 pandemic. Therefore, the FDA is deferring action on the application until an inspection can be completed. The company will continue to work actively with the FDA to define an approach for scheduling the required inspection. Spectrum has confirmed with the FDA that this is not a Complete Response Letter.
>
> "We are actively working with the FDA to find a way to expedite the plant inspection," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "The manufacturing facility is ready for inspection and we are eager to assist the FDA in completing their assessment as soon as possible."

71. On November 4, 2020, Spectrum issued a press release announcing the Company's Q3 2020 financial results and corporate update. The press release stated, in relevant part:

> "The third quarter was marked by significant progress in our drug development programs and a strengthened financial position," said Joe Turgeon, President and CEO, Spectrum Pharmaceuticals. "Our team is preparing for the upcoming pre-NDA meeting with the FDA for poziotinib and actively working to obtain an approval for ROLONTIS as soon as possible."
>
> * * *
>
> ***ROLONTIS (eflapegrastim), a novel long-acting G-CSF***

> The FDA deferred its action on the BLA for ROLONTIS, due to an inability to inspect the Hanmi Bioplant in South Korea citing travel restrictions related to the COVID-19 pandemic.
>
> Spectrum has confirmed with the FDA that the deferral is not a Complete Response Letter (CRL). The company is actively working to find a way to expedite the plant inspection.

72. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q3 2020 results (the "Q3 2020 Earnings Call"). During the scripted portion of the Q3 2020 Earnings Call, Defendant Turgeon stated, in relevant part:

> We have answered all the inquiries from the FDA, and we're not aware of any outstanding items other than the inspection. We will be prudent with our financial resources and have gated certain activities pending further feedback or action from the FDA. Regarding the ROLONTIS plant inspection, our partner Hanmi Pharmaceuticals is a well-established global biopharmaceutical player with a world-class manufacturing facility.
>
> Hanmi is the second largest pharmaceutical company in Korea, behind only Samsung. They're prepared for the inspection and willing to be accommodative to the needs of the FDA as it strives to meet the regulatory obligations. They've been a great partner and are working in tandem which Spectrum to obtain an approval for ROLONTIS as soon as it is possible. I'm real confident in our ability to meet our corporate objectives in advance of programs with the aspiration of bringing new treatments to the patients with cancer, who needed it.

Further, when asked a question regarding mock inspections of the ROLANTIS manufacturing facility, Defendant Lebel responded, in relevant part:

> So, as we've indicated in my remark, and [Defendant Turgeon's], the – look to our knowledge, right, we have received during the review of this file many questions, we believe that we've answered all of them. And that the FDA was satisfied. But of course, we don't know that until, you know, they approved this drug. To our knowledge, the only thing outstanding right now, is the inspection of our manufacturing, a main manufacturing plant.

In response to that same question, Defendant Turgeon stated, in relevant part:

> And I want to stress another thing, we are absolutely ready for this inspection. We are ready for a long time, we welcome it. Matter of fact, the third part of your question was the mock inspections, was it required? They're certainly not required by the agency. We do that to make sure we're ready. And I can tell you, we have Spectrum boots on the ground there, we

> have Hanmi, which I mentioned, is a world-class manufacturer with a world-class plant. Their people are ready, and we work very closely with them with these mock inspections.
>
> And we have a third leg to the stool, we have outside experts, we've hired to run these, not only run these mock inspections, but also help the readiness. And these are people who have done this for a living. They do this – they know exactly what the FDA is looking for in an inspection. So, we feel we're ready. We welcome the inspection already, you know, we can't wait.

Finally, when asked what the "cadence of discussions with the FDA" was at that moment, Defendant Turgeon responded, in relevant part:

> They have the authority to do things. So, you know, like in anything else, you contact the agency, they have so much time to get back to you. Kind of that's all laid out. And then we you know, we certainly can have discussions on what's next, how can we work with you, we're willing to do whatever it takes. As [Defendant Lebel] said, just yesterday, they issued, you can see movement on their part for the first time in this because this is new to them. And they issued the statement on moving forward. Europe's doing it, as you heard already.
>
> So I think they're going to have to just start moving forward. And all I'll tell you is, we will do anything we can to, I'll use the word nudge them. You know, you have to do it properly, but we every right to talk to them, we're ready to go and try and figure out how to do this as quickly as possible.

73. On March 16, 2021, Spectrum issued a press release providing an update on the ROLONTIS pre-approval inspection. The press release stated, in relevant part:

> Spectrum [. . .] today announced that the U.S. Food and Drug Administration (FDA) has scheduled the pre-approval inspection at the ROLONTIS® (eflapegrastim) manufacturing site in May 2021. In October 2020, the company received notification from the agency that it would defer its decision on the BLA because an inspection of the Hanmi Bioplant in South Korea could not be conducted during the review cycle due to restrictions on travel related to the COVID-19 pandemic.
>
> "I am thrilled that the FDA informed us that they will be conducting a preapproval inspection of the ROLONTIS manufacturing facility in May," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "We believe the pre-approval inspection marks the final step in the ROLONTIS review process."

74. On March 30, 2021, Spectrum issued a press release announcing the Company's Q4 and full year 2020 financial results and pipeline update. The press release stated, in relevant part, "[. . .] we are delighted that the FDA has scheduled the pre-approval inspection at the ROLONTIS manufacturing facility for May 2021. The company has made tremendous progress advancing our development programs and conducting our clinical trials, despite the challenges of the global pandemic. I am proud of our employees who demonstrated resiliency and creativity during these unprecedented times."

75. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q4 and full year 2020 results (the "Q4 2020 Earnings Call"). During the scripted portion of the Q4 2020 Earnings Call, Defendant Turgeon stated, in relevant part:

> Regarding ROLONTIS, the FDA is scheduled to perform the pre-approval inspection of our manufacturing facility in May. As you may recall, FDA informed us last year that it was deferring action on the BLA due to their inability to inspect the Hanmi Bioplant in South Korea as a result of travel restrictions related to the COVID-19 pandemic.
>
> Hanmi Pharmaceuticals is an experienced biopharmaceutical manufacturer with a world-class facility, and they are ready for this inspection. As a matter of fact, Hanmi has received recently approval for ROLONTIS in Korea, which further raises our confidence in their manufacturing readiness.
>
> * * *
>
> I think you can see from everyone's remarks that Spectrum continues to make strong and steady progress on our pipeline. We look forward to the completion of the inspection of our ROLONTIS manufacturing facility.

Also during the scripted portion of the Q4 2020 Earnings Call, Defendant Lebel stated, in relevant part:

> Our BLA for ROLONTIS is supported by robust clinical data from two large randomized clinical trials. Regarding the deferred action on our ROLONTIS filing that Joe mentioned, we believe with that we have answered satisfactorily all questions from the FDA related to the review of the BLA, and we believe that the inspection represents the final step in the review process. We and our partner Hanmi

> are ready for the FDA preapproval planned inspection that has been scheduled for May.

Finally, when asked to provide clarity on the "specific next steps after the [ROLANTIS facility] inspection," Defendant Lebel stated, in relevant part:

> So let me start with -- let's just say that when we got the deferral as opposed to a complete response CRL that usually indicates that the FDA is, they are pausing their review and the only step left to our knowledge is the inspection.
>
> We have had a lot of discussion with the FDA on all the other matters, and our understanding is that we have answered all their questions satisfactorily. So, we believe the inspection is fundamentally the last step.
>
> As to the timing following an inspection assuming that there's no issues, roughly I think a little more than a month, probably[.]

76. On March 31, 2021, Spectrum filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K listed as one of the recent highlights of the Company's business:

> ***ROLONTIS, a novel long-acting G-CSF:***
>
> We submitted our updated BLA for ROLONTIS to the FDA on October 24, 2019, which was accepted for review by the FDA on December 20, 2019. Our BLA is supported by data from two similarly designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy. On October 26, 2020, we announced that the FDA PDUFA target action date set for October 24, 2020 was deferred pending inspection of the Hanmi manufacturing facility in Korea due to COVID-19 related travel restrictions. In March 2021, the FDA scheduled the pre-approval inspection of the Hanmi manufacturing facility for May 2021.

77. Appended to the 2020 10-K as exhibits were signed certifications pursuant to SOX by Defendants Turgeon and Gustafson, attesting that "the information contained in the [2020 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

78. On May 13, 2021, Spectrum issued a press release announcing the Company's Q1 2021 financial results and corporate update. The press release stated, in relevant part, "[w]e also look forward to the FDA's pre-approval inspection of the ROLONTIS manufacturing facility which has been scheduled for later this month," and "[t]he FDA's pre-approval inspection of the ROLONTIS manufacturing facility has been scheduled for later this month and pre-commercial preparation activities are underway."

79. That same day, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q1 2021 results (the "Q1 2021 Earnings Call"). During the scripted portion of the Q1 2021 Earnings Call, Defendant Turgeon stated, in relevant part:

> Now, regarding ROLONTIS, the FDA scheduled the pre-approval inspection of our manufacturing facility for later this month. We believe this inspection marks the final step in the approval process and that Hanmi's world class facility is ready for this inspection. We are making real progress on our two lead clinical programs with major catalysts expected in the coming months, including a launch and an NDA filing.
>
> * * *
>
> Spectrum continues to make strong and steady progress on our development pipeline. We look forward to the completion of the inspection of our ROLONTIS manufacturing facility, which is planned to begin shortly.

Also during the scripted portion of the Q1 2021 Earnings Call, Defendant Lebel stated, in relevant part, "[n]ow, let me shift to ROLONTIS. On the regulatory side, [Defendant Turgeon] has already updated you on the status of the pre-approval inspection and we remain confident that our preparation with our partner, Hanmi, should result in a positive outcome for this FDA plant inspection." Further, when asked about the next steps after the pre-approval inspection of the ROLONTIS manufacturing plant, Defendant Turgeon responded, in relevant part, "[w]e're prepared for the inspection. We're looking forward to it. I can't give you an exact date, but I think the FDA would take a reasonable amount of time to get back to us once the inspection is done and

we feel that's the last step. So without giving the exact time, I think it'll be a reasonable amount of time after the inspection is done."

80. The above referenced statements were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the ROLONTIS manufacturing facility maintained deficient controls and/or procedures; (ii) the foregoing deficiencies decreased the likelihood that the FDA would approve the ROLONTIS BLA in its current form; (iii) Spectrum had therefore materially overstated the ROLONTIS BLA's approval prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

81. On August 6, 2021, the Company announced receipt of a CRL from the FDA regarding the ROLONTIS BLA. Specifically, the press release stated:

> The CRL cited deficiencies related to manufacturing and indicated that a reinspection of the Company's manufacturing facility will be necessary. The company is seeking further clarification from the FDA and plans to meet with the agency as soon as possible.
>
> "We are disappointed with this outcome and look forward to fully understanding the remediation timelines for the program," said Joe Turgeon, President and CEO of Spectrum Pharmaceuticals. "We continue to believe in ROLONTIS and plan to diligently complete the regulatory process to bring ROLONTIS to market."

82. On this news, the Company's stock price fell $.070 per share, or 21.54%, to close at $2.55 per share on August 6, 2021.

DAMAGES TO THE COMPANY

83. Spectrum has been, and will continue to be, severely damaged and injured by the

Defendants' misconduct. As a direct and proximate result of the Defendants' conduct, Spectrum has been seriously harmed and will continue to be. Such harm includes, but is not limited to:

a. costs incurred in compensation and benefits paid to Defendants that breached their fiduciary duties and violated federal securities laws;

b. substantial loss of market capital;

c. costs already incurred and to be incurred defending the Related Securities Class Action and;

d. any fines or other liability resulting from the Company's violations of federal law.

84. In addition, Spectrum's business, goodwill and reputation with its business partners, regulators and shareholders have been gravely impaired. The credibility and motives of management are now in serious doubt.

85. The wrongdoing complained of herein has irreparably damaged Spectrum's corporate image and goodwill. For at least the foreseeable future, Spectrum will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Spectrum's ability to raise equity capital or debt on favorable terms in the future is now impaired.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

86. Plaintiff brings this action derivatively in the right and for the benefit of Spectrum to redress injuries suffered, and to be suffered, by Spectrum as a direct result of violations of federal securities laws by the Defendants. Spectrum is named as a Nominal Defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

87. The Board of Spectrum, at the time this action was commenced, consisted of Defendants Ashton, Brennan, Fischer, Lim, Riga, Vacirca, Vyas, and Welles, a total of eight (8) individuals.

88. Plaintiff has not made any demand on the Board to institute this action because a pre-suit demand on the Spectrum Board would be futile, and therefore, excused. This is because a majority of the Board faces a substantial likelihood of liability as a result of their scheme and false and misleading statements and/or omissions of material adverse facts which render them unable to impartially consider a demand to pursue the wrongdoing alleged herein.

89. Each of the Director Defendants were responsible for reviewing and approving the Company's public statements made in press releases and financial filings with the SEC throughout the Relevant Period. By authorizing the false and misleading statements and material omissions and described above during the Relevant Period concerning the Company's business and prospects, each of the Director Defendants knowingly faces a substantial likelihood of liability for their participation in the illicit acts alleged herein.

90. Upon information and belief, in their capacity as members of the Company's Board, the Director Defendants were privy to specific information related to the Company's business and financial prospects, which would reasonably put them on notice that the statements they were making were in fact false and misleading.

Demand is Demand is Futile as to Defendant Riga Because His Principal Professional Occupation as the Company's CEO and President

91. Defendant Riga is and has been the Company's President, CEO, and member of the Board since January 2022. Previously, Defendant Riga served as the Company's Chief Commercial and Chief Operating Officer. In his role as Chief Operating Officer of Spectrum for fiscal years 2018, 2019, and 2020, Defendant Riga received $5,299,288, $3,817,961, and

$2,522,799 in total compensation respectively. Further, in connection with his new role as the Company's CEO, Defendant Riga will receive an annual salary $650,000 and will be entitled to an annual discretionary bonus of up to 70% of his base salary, as determined by the Board. The Company does not claim that Defendant Riga is an independent director and because his primary source of income and primary employment is his employment as CEO of Spectrum and his professional reputation is inextricably bound to his role at Spectrum, Defendant Riga is incapable of acting independently and demand is futile upon him.

Demand is Futile as to the Members of the Audit Committee

92. Demand is futile as to Defendants Ashton, Brennan, Fischer, and Welles (the "Audit Committee Defendants") as members of the Audit Committee during the Relevant Period for their knowing failure to fulfill their responsibilities.

93. The Board of Directors adopted an Audit Committee Charter, setting forth the responsibilities of the Audit Committee. The Audit Committee Charter notes that the purpose of the Audit Committee shall be to "assist the Board in its general oversight of the Company's accounting and financial reporting processes, audits of the financial statements, internal control and audit functions, and compliance with legal and regulatory requirements."

94. Upon information and belief, in their capacity as members of the Audit Committee, the Audit Committee Defendants were privy to specific information related to the Company's business, operations, and prospects, which would reasonably put them on notice that the statements set forth above in the Company's public filings were materially false and misleading when made.

95. The Company's public filings concerning the Company's business and prospects during the Relevant Period contained materially misleading information and/or omitted material information. In their capacity as members of the Audit Committee, the Audit Committee

Defendants were charged with ensuring that these reports did not contain such materially misleading information. By allowing documents to be filled with misleading information, the Audit Committee Defendants face a sufficiently significant likelihood of liability so as to render them interested. Accordingly, the Audit Committee Defendants cannot adequately independently consider a demand.

Demand is Futile as to the Director Defendants

96. Plaintiff has not made any demand on the Board to institute this action because a pre-suit demand on the Company's Board would be futile, and therefore, excused. This is because a majority of the Board faces a substantial likelihood of liability as a result of their knowing toleration of the above described false and misleading statements and omissions of material adverse facts, which render them unable to impartially consider a demand to pursue the wrongdoing alleged herein.

97. Upon information and belief, in their capacity as members of the Company's Board, the Director Defendants were privy to specific information related to the Company's business and financial prospects, which would reasonably put them on notice that the statements they were making were in fact false and misleading.

98. Each of the Director Defendants were responsible for reviewing and approving the Company's public statements made in press releases and financial filings with the SEC throughout the Relevant Period. By authorizing the false and misleading statements and material omissions and described above during the Relevant Period concerning the Company's business and prospects, each of the Director Defendants knowingly faces a substantial likelihood of liability for their participation in the illicit acts alleged herein.

99. Accordingly, the Director Defendants face a sufficiently substantial likelihood of

liability such as to create a reasonable doubt as to their impartiality to consider a demand to sue themselves in the present action.

COUNT I

Against the Officer Defendants for Contribution Under Section 10(b) of the Exchange Act, Rule 10b-5 Promulgated Thereunder, and/or Section 20(a) of the Exchange Act

100. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

101. As a result of the conduct and events alleged above, Spectrum has been named as a defendant in the Related Securities Class Action brought on behalf of Spectrum shareholders in which it is a joint tortfeasor in claims brought under Section 10(b) of the Securities and Exchange Act and Rule 10(b)-5 promulgated thereunder.

102. Federal law provides Spectrum with a cause of action against other alleged joint tortfeasors under Rule 10b-5. In particular, under the Supreme Court's decision in *Musick, Peeler & Garrett v. Employers Insurance of Wausau*, 508 U. S. 286, Spectrum has a federal law right of contribution against joint tortfeasors under Rule 10b-5. Section 21D(f) of the Securities and Exchange Act further sets forth specific provisions entitling Spectrum to contribution against all joint tortfeasors under Rule 10b-5, regardless of whether they have been named as defendants in the currently pending Related Securities Class Action, and sets forth specific rules regarding the determination of claims for such contribution.

103. Accordingly, Plaintiff, on behalf of Spectrum, hereby claims contribution against the Officer Defendants, each of whom has been named in the currently pending Related Securities Class Action as a joint tortfeasor with Spectrum under Rule 10b-5, or if joined in such actions, would be liable for the same damages as Spectrum.

104. Spectrum claims no right to indemnification under the federal securities laws from them in this count, but rather only claims contribution.

Allegations Regarding the Officer Defendants

105. Throughout the Relevant Period, the Officer Defendants caused the Company to issue false and misleading statements and/or omit material information in public statements and/or Company filings concerning the Company's business and financial prospects. These statements were materially misleading to persons who purchased Spectrum securities during the Relevant Period.

106. Specifically, during the Relevant Period, the Officer Defendants made or allowed the Company to make false and/or misleading statements and/or failed to disclose that: (i) the ROLONTIS manufacturing facility maintained deficient controls and/or procedures; (ii) the foregoing deficiencies decreased the likelihood that the FDA would approve the ROLONTIS BLA in its current form; (iii) Spectrum had therefore materially overstated the ROLONTIS BLA's approval prospects; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

107. The plaintiffs in the Related Securities Class Action allege that they relied, directly or indirectly, upon these false statements and misleadingly omissive disclosures in purchasing Spectrum securities, and, as a result, suffered damages because value of their investments was distorted by the false and materially omissive statements, and they purchased such securities at such distorted prices.

108. The damages suffered by said investors were caused by reason of the fact that (i) they were induced to purchase said securities by the false and misleading statements alleged herein, and (ii) the reveal of the true nature of the Company's business and prospects resulted in the

decrease in price of its securities, causing the value of shareholders investments to drop.

109. The plaintiffs in the Related Securities Class Action were unaware of the false and misleading nature of said statements and omissive disclosures.

110. When the Officer Defendants signed off on or made the false statements and omissive disclosures detailed herein, they had actual knowledge that they were false and misleading. As alleged in detail herein, due to their positions as employees and/or directors of Spectrum, the Officer Defendants were privy to information regarding the Company's business and financial prospects and would have been aware that the statements made were in fact false and misleading when made.

111. Accordingly, the Officer Defendants are liable for damages under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, and, if Spectrum were to be held liable in the Related Securities Class Action, the Officer Defendants would be liable to it for contribution. Plaintiffs hereby derivatively claim such right of contribution on behalf of Spectrum.

Allegations Regarding the Officer Defendants as Control Persons

112. In acting as alleged above, the Officer Defendants were acting as authorized agents of Spectrum in their roles as directors and/or employees. Because of their positions of control and authority as senior officers and/or directors, the Officer Defendants were able to, and did, control the contents of the various reports, press releases and public filings disseminated by the Company throughout the Relevant Period, as alleged herein.

113. The Officer Defendants were "controlling persons" of Spectrum within the meaning of Section 20(a) of the Exchange Act, and, accordingly, the Officer Defendants could be held liable to the plaintiffs in the Related Securities Class Action. Were the Company to be held liable in said Related Securities Class Action, the Officer Defendants would be liable to it for

contribution.

114. Plaintiff hereby derivatively claims such right of contribution on behalf of Spectrum.

COUNT II

Against the Individual Defendants for Breaches of Fiduciary Duty

115. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

116. The Individual Defendants owed and owe Spectrum fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Spectrum the highest obligation of good faith, loyalty, and due care.

117. The Individual Defendants have violated and breached their fiduciary duties of good faith, loyalty, and due care by causing or allowing the Company to disseminate to Spectrum shareholders materially misleading and inaccurate information through the Company's SEC filings throughout the Relevant Period. These actions could not have been a good faith exercise of prudent business judgment.

118. During the course of the discharge of their duties, the Individual Defendants knew or recklessly disregarded the unreasonable risks and losses associated with their misconduct, yet the Individual Defendants caused Spectrum to engage in the conduct complained of herein which they knew had an unreasonable risk of damage to the Company, thus breaching their duties owed to Spectrum and its shareholders. As a result, the Individual Defendants grossly mismanaged the Company.

119. As a direct and proximate result of the Individual Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the

misconduct alleged herein, the Individual Defendants are liable to the Company.

120. Plaintiff, on behalf of Spectrum, has no adequate remedy at law.

COUNT III

Against the Individual Defendants for Unjust Enrichment

121. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

122. By his wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of Spectrum.

123. The Individual Defendants were unjustly enriched as a result of the compensation they received while breaching their fiduciary duties owed to Spectrum.

124. Plaintiff, as a shareholder and representative of Spectrum, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, benefits, and other compensation obtained by the Individual Defendants from their wrongful conduct and breaches of fiduciary duty.

125. Plaintiff, on behalf of Spectrum, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in the Company's favor against all Defendants as follows:

A. Declaring that Plaintiff may maintain this action on behalf of Spectrum and that Plaintiff is an adequate representative of the Company;

B. Determining and awarding to Spectrum the damages sustained by it as a result of the violations set forth above from each of the Defendants, jointly and severally, together with interest thereon;

C. Directing Spectrum and the Director Defendants to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Spectrum and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote the following resolutions for amendments to the Company's By-Laws or Articles of Incorporation; and the following actions as may be necessary to ensure proper Corporate Governance Policies:

(1) a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board; and

(2) a proposal to ensure the establishment of effective oversight of compliance with applicable laws, rules, and regulations.

D. Determining and awarding to Spectrum exemplary damages in an amount necessary to punish Defendants and to make an example of Defendants to the community according to proof at trial;

E. Awarding Spectrum restitution from Defendants, and each of them;

F. Awarding Spectrum Contribution from the Officer Defendants, and each of them;

G. Awarding Plaintiff the costs and disbursements of this action, including reasonable attorneys' and experts' fees, costs, and expenses; and

H. Granting such other and further equitable relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: April 28, 2022

Respectfully submitted,

BIELLI & KLAUDER, LLC

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